DECLARATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : 09/630,333 Serial No:

Filed: July 31, 2000 Examiner:

For:

Attorney docket:

Assistant Commissioner for Patents
Washington, D.C. 20231

I, Rama Mukherjee, M.Sc., Ph.D., FNASc, Director, Dabur Research Foundation, a citizen of India with major contribution in the field of cancer therapeutics, neurobiology, and mycobacterial immunology, and having filed more than 30 patent applications and with over hundred publications in international and national journals declare that I have read and understood the specification of US patent application.

The following experiment was conducted.

Example

Pharmaceutical composition and method of administration to a patient for treatment of cancer

The invention provides a method for treating a mammal (including a human being) afflicted with cancer. The types of cancer that may be treated include, but are not necessarily limited to, cancers of breast, pancreas, stomach, oral, lung, colon, ovary leukemia, prostate, glioblastoma, and larynx .

The method of this invention comprise, consist of, or consist essentially of

administering systemically to the mammal a therapeutically effective dose of peptide SEQ ID : 3, SEQ ID : 4, SEQ ID : 5, SEQ ID : 6, SEQ ID : 7 SEQ ID : 8, SEQ ID : 9, SEQ ID : 10, SEQ ID : 11, SEQ ID : 12 or SEQ ID : 13. The dose of the peptide ranges between 0.25 µg /Kg. BWt to 500 µg /Kg. BWt, and more preferably in the range of 10 µg /Kg. BWt to 200 µg /Kg. BWt. However, the dose dependent on the effects sought, the manner of administration, the peptide selected, and the cancer being treated. Systemic administration refers to oral, rectal, nasal, transdermal, and parentral (i.e., intramuscular, intravenous, and subcutaneous). In accordance with good clinical practice, it is preferred to administer the composition at a dose that will produce anticancer effects without causing undue harmful side effects. The composition may be administered either alone or as a mixture with other therapeutic agents.

The composition may optionally and preferably contain pharmaceutically acceptable diluents, excipients, solvents, binders, stabilizers, and the like. Such diluents may include: RPMI 1640, buffered saline, isotonic NaCl, Ringer's solution, water, distilled water, polyethylene glycol (neat or in water), 2% tween in water, dimethylsulfoxide to 50% in water, propylene glycol (neat or in water), phosphate buffered saline, balanced salt solution, glycerol, and other conventional fluids that are suitable for intravenous administration. Pharmaceutical compositions, which provide from about 0.1 to 10.0 mg of the composition per unit dose are preferred and are conventionally prepared as tablets, lozenges, capsules, powders, aqueous or oily suspensions, syrups, elixirs, and aqueous solutions. The nature of the pharmaceutical composition employed will, of course, depend on the desired route of administration

<u>Protocol and method of treating an animal with cancer using SEQ ID : 11</u>

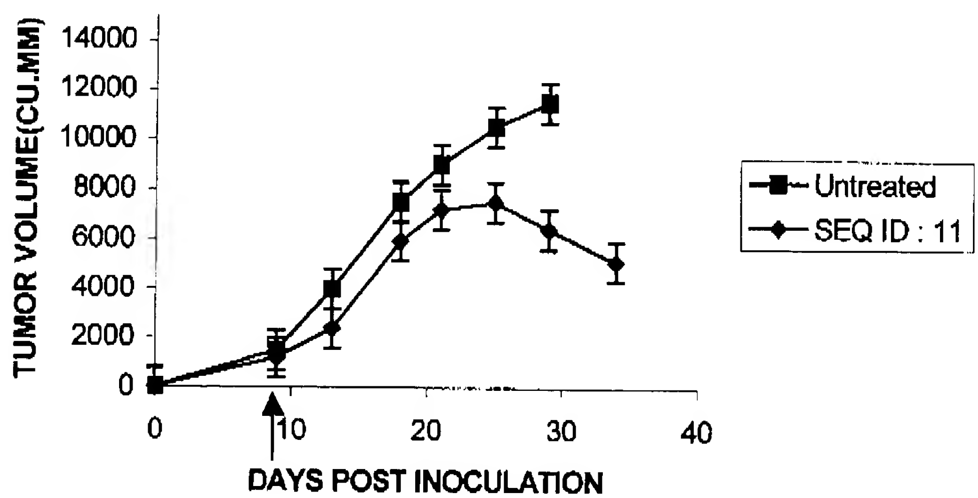
Primary tumor cells of colon adenocarcinoma (PTC) xenografts were initiated in Balb/c athymic mice by subcutaneous inoculation of a single cell suspension of PTC cells(15 X 10^6 cells/100 µL). When the average tumor volumes, as measured using a vernier caliper, were between 400 – 800 mm^3 treatment was initiated on the tumor

bearing animals which were divided into two groups of three animals each including one untreated control group. SEQ ID : 11 was prepared at a concentration of 42.5 μg/ml by solubilizing the said amount of peptide in water. The solubilized peptide was administered intravenously at a dose of 4.25 μg/100 μL twice a day. The antitumor activity was monitored by measuring tumor volumes every fourth day using the formula W*W*L*0.4 (W = smaller dia, L = larger dia). It may be noted that all control (untreated) animals died by day 29 post treatment. The percentage inhibition of tumor growth was calculated using the formula (1- tumor volume(treated) / tumor volume (control))* 100.

The results are:

Adjoining figure shows the pattern of tumor growth till day 34 in treated and day 29 in untreated animals. The percentage inhibition of tumor growth caused by SEQ ID : 11 as compared to untreated on day 29 was 53%.

INVIVO ANTITUMOR EFFECT OF SEQ ID : 11(Dose x = 8.5 ug/day) ON PTC XENOGRAFTS



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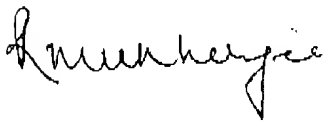
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statement may jeopardize the validity of the application or any patent issued thereon.

Signed this14th day of February 2003.

Signature



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che mo ther a py

(click to hear the word) (kē'mō-thĕr'ə-pē, kĕm'ə-)
n.

1. The treatment of cancer using specific chemical agents or drugs that are selectively destructive to malignant cells and tissues.
2. The treatment of disease using chemical agents or drugs that are selectively toxic to the causative agent of the disease, such as a virus, bacterium, or other microorganism.

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che'mo ther'a peu'tic
(-pyōō'tĭk) ***adj.***
che'mo ther'a peu'ti cal ly ***adv.***
che'mo ther'a pist ***n.***

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